K003371

Section II 510(k) Summary and Certification

DEC 21 2000

Pump Tubing with X-Coating

Submitter Information:

Name and Address:
Olson Medical Sales, Inc.
28 Howe Street
Ashland, MA 01721

Contact Person:
Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: September 30, 2000

Device Names:

Proprietary Name: Pump Tubing with X-Coating
Common Name: Pump Tubing
Classification Name: Tubing, Pump, Cardiopulmonary Bypass

Predicate Device:

The Pump Tubing with X-Coating that is the subject of this premarket notification is substantially equivalent to the predicate device; the uncoated tubing, which is legally marketed and has been in interstate commerce prior to May 28, 1976. As such, the predicate tubing is considered to have *preamendment* status.

Intended Use:

The Pump Tubing with X-Coating is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures. The tubing is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

The tubing is intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surface of the tubing is coated with X-Coating, which is a biocompatible coating that is applied to the device to reduce the adhesion of platelets to the device surface.

Principles of Operation and Technology:

The pump tubing that is the subject of this premarket notification is used in a pump head and becomes cyclically compressed by the pump to cause the blood to flow through the bypass circuit. When not routed through the pump head, the tubing provides a conduit for the flow of blood throughout the circuit.

Design and Materials:
Each size of the Pump Tubing with X-Coating that is included in this submission is comprised of polyvinylchloride (PVC). The tubing ranges in size from a ¼" inside diameter to ½" in diameter. The durometer measurements range from Shore A-65 to Shore A-70.

Each tubing size is coated with a biocompatible polymer coating (X-Coating) that is intended to reduce the adhesion of platelets to the internal surface of the tubes as blood flows through the circuit.

Performance Evaluations:
The performance of the Pump Tubing with X-Coating submitted in this premarket notification is substantially equivalent to the performance of the uncoated pump tubing. The following tests were conducted to demonstrate equivalence in performance:

- Visual Examinations
- Dimensional Analysis
- Leakage Testing
- Effects Upon Cellular Components (Hemolysis)
- Flow Rate Testing
- Durability Testing
- Spallation Evaluation
- Thrombus Formation (Visual)

Substantial Equivalence Comparison:
The Pump Tubing with X-Coating is substantially equivalent to the uncoated pump tubing as follows:

- Intended Use: Both the Pump Tubing with X-Coating and the uncoated pump tubing are intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary procedures. Each tubing is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

- Principles of Operation and Technology: The Pump Tubing with X-Coating and the uncoated pump tubing each utilize the same technologies in the operation of the devices. They are each used in a pump head and become cyclically compressed by the pump to cause the blood to flow through the bypass circuit. When not routed through the pump head, the tubing provides a conduit for the flow of blood throughout the circuit.

- Design and Materials: The design and the materials of the Pump Tubing with X-Coating and the uncoated tubing are exactly the same with the exception of the X-Coating polymer that is applied to the coated tubing.

- Performance: Comparisons of the performance of the Pump Tubing with X-Coating and the uncoated pump tubing were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

Substantial Equivalence Summary:
In summary, the Pump Tubing with X-Coating and the uncoated tubing are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Olson Medical Sales, Inc. conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Olson Medical Sales, Inc. conducted studies for materials characterization, including physico-chemical profiles and FT-IR scans.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

- Safety evaluations of the polymer coating were conducted by Terumo Corporation (Japan). Those studies include:

  - Acute Systemic Toxicity Testing (in Rats)
  - Genotoxicity Testing – Bacterial Reverse Mutation
  - Genotoxicity Testing – Chromosome Aberration
  - Sensitization (in Guinea Pigs)

- *In Vitro* studies using human blood were conducted to demonstrate the hemocompatiblity of the polymer coating.

Conclusion:
In summary, the Pump Tubing with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated tubing which has *preamendment* status (is legally marketed and was in interstate commerce prior to May 28, 1976).

Olson Medical Sale's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

TERUMO Cardiovascular Systems
c/o Mr. Garry A. Courtney
Regulatory Affairs Specialist
OMS/TCVS
125 Blue Ball Road
Elkton, MD. 21921

Re: K003371
Trade Name: Pump Tubing with X-Coating
Regulatory Class: II (two)
Product Code: DWF
Dated: October 27, 2000
Received: October 30, 2000

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): _____

Device Name: Pump Tubing with X-Coating

Indications For Use:
Intended Use Described In The 510(k):

The *Pump Tubing with X-Coating* is intended to provide a conduit for extracorporeal blood flow through a roller pump during cardiopulmonary bypass procedures. The *tubing* is also intended to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit.

The *tubing* is intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surface of the tubing is coated with X-Coating, which is a biocompatible coating that is applied to the device to reduce the adhesion of platelets to the device surface.

Garry J. Courtney 10/27/2000

Garry A. Courtney
Regulatory Affairs
Olson Medical Sales, Inc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003371

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)